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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,018	05/31/2001	Stephen William Watson Michnick	ODDY 002	8430

7590

03/02/2004

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EXAMINER
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FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/870,018

Applicant(s)

MICHNICK ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 18-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 43-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-17 and 43-62 in the paper filed November 20, 2003 is acknowledged. The traversal is on the ground(s) that the climate for restrictions has changed and requests that restriction practice be abolished. Further, Applicant argues that there is unity of invention standard be applied. This is not found persuasive because it is not directed towards the proper issues. This is a U.S. application filed under 35 U.S.C. 111 and not under 35 U.S.C. 371, so unity of invention standard does not apply. Second, the restriction clearly demonstrated both why the inventions are distinct and why a burden is present for searching. This is sufficient to meet the requirements for a proper restriction under the Manual of Patent Examining Procedure.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

2. Claims 1-14, 6-7, 43-46, 48-53, 54-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the terms "penicillin-class substrate" and "cephalosporin-class substrate". The issue is not solely one of breadth but rather one of definition, since there is no way to determine from the specification what compounds are "penicillin-class substrates" or "cephalosporin-class substrates". While penicillin itself is clearly such a substrate, for example, what about ampicillin? Further

what about unrelated antibiotics that do not have a lactam ring? Alternatively, what about undescribed and unknown lactam ring antibiotics? In fact, the terms do not require the compound to have any particular activity or structure so bleach is has antimicrobial activity and might be a "penicillin-class substrate" and a "cephalosporin-class substrate". Consequently, in the absence of any clear definition in the specification of what these terms encompass, the issue is that it cannot be determined what compounds are embodied by the claim. Therefore, the claim terms are vague and indefinite.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-17 and 43-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Cornish (US 2002/0004202 A1).

Cornish teaches an assay method of claims 1, 8, 12, 43, 56, comprising (see abstract).

(A) generating:

1) at least a first fragment of a reporter molecule linked to a first interacting domain and at least a second fragment of a reporter molecule linked to a second

interacting domain, (see page 5, paragraphs 81-83, pages 12-14, example 2) or  
2) nucleic acid molecules that code for A)1) and subsequently allowing said  
nucleic acid molecules to produce their coded products (see page 10, paragraph  
0172 which shows nucleic acid encoding protein chimeras); then,  
(B) allowing interaction of said domains (see page 5, paragraph 083 and page  
14, paragraph 0214; and  
(C) detecting reconstituted reporter molecule activity (see page 5, paragraph  
0084 and page 14, paragraphs 0215-0219),  
where said reporter molecule can react with a penicillin- or cephalosporin-class  
substrate (see page 14, paragraph 0215, where nitrocefin, cephalosporinase  
substrate is used).

With regard to claims 2-3, 44-45, Cornish teaches the use of the enzyme, Q908R  
cephalosporinase (see page 14, paragraph 0214, 0216).

With regard to claim 4, 46, Cornish teaches hydrolyzing the cephem linkage,  
which is irreversible (see page 14, paragraph 0216).

With regard to claims 5, 11, 47, 54, Cornish teaches the use of Nitrocefin as a  
substrate (see page 14, paragraph 0215).

With regard to claim 6, 48, Cornish teaches an in vivo two hybrid assay (see  
page 13, paragraph 0212).

With regard to claim 7, 49, Cornish teaches the use of the Q908R  
cephalosporinase (see page 14, paragraph 0214, 0216), which is not normally  
present in eukaryotes.

With regard to claim 9, 50-52, Cornish demonstrates a signal to noise ratio of more than 30 (see figure 18).

With regard to claim 10, 12, 53, 55, Cornish teaches a signal, blue color colonies, which can be observed by eye (and whose signal is entrapped in the cells) (see figures 14 and 15).

With regard to claims 13-14, 57-59, Cornish teaches the use of fluorescent signals (see paragraph 0127).

With regard to claim 15, 60, 62, Cornish teaches screening for compounds that inhibit binding (see paragraph 0122).

With regard to claims 16-17, 61, Cornish teaches that selection can be based upon survival and growth (see paragraph 0222).

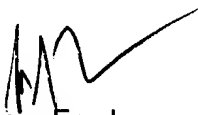
With regard to claims 43-62, Cornish teaches two molecules linked together (see paragraph 0015).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman  
Primary Examiner  
Art Unit 1634